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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/993,086	11/06/2001	Todd K. Whitehurst	AB-135U	7480

23845 7590 12/03/2003

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EXAMINER	
MACHUGA, JOSEPH S	
ART UNIT	**PAPER NUMBER**
3762	

DATE MAILED: 12/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/993,086	WHITEHURST, TODD K.
	Examiner	Art Unit
	Joseph S. Machuga	3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-33 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-33 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3&4.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1-3, 5-25, 27-30, 32 and 33 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1,2,3, 21, 1, 4-8, 10-21, 23-25, 27-30, 34 and 35 respectively of copending Application No. 09993085. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between the claims namely to "a method of treating patients with eating disorders" as opposed to a method of preventing diabetes" and "modulate" as opposed to "inhibit" are considered functionally equivalent.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 6, 16-19, 21, are rejected under 35 U.S.C. 103(a) as being unpatentable over Rise #5782798 in view of Fischell #6006124.

3. Rise discloses a method and apparatus for treating the eating disorder of obesity. The device includes two system control units (100, 16), electrodes (38, 40) and an implantable pump. The system delivers electrical stimulation and therapeutic dosages of one or more drugs to the lateral hypothalamus; paraventricular nucleus or the ventral medial hypothalamus (column 3, lines 12+; column 5, lines 19+.) The reference also notes (Table IV) that low frequency pulses (below 100hz) and high frequency pulses (above 100hz) can activate portions of the brain. Not disclosed by this reference is the step of implanting the control system in the skull or brain of the patient.

Fischell discloses a deep brain electrode. The reference teaches that the control module can be implanted directly into the skull of the patient. This eliminates frequent

bending of the wires leading from the control module to the electrodes in the prior art systems.

Given Fischell's teaching it would have been obvious to one of ordinary skill in the art to implant the control modules in Rise's device within the skull of the patient to prevent bending of the wires that could lead to eventual breakage.

4. Claims 1-4, 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rise #5782798 in view of Fischell #6006124 as applied to claims 6 above, and further in view of Frankish et al (Neuropeptide Y, The Hypothalamus, and Diabetes: Insights Into the Central Control of Metabolism – article.)

Frankish et al teaches (page 763, second full paragraph) that neuropeptide Y (NPY) is an obvious candidate for mediating the hypothalamic of insulin deficient diabetes and obesity and that significantly higher NPY concentrations exists in the arcuate nucleus, paraventricular nucleus and the dorsal medial nucleus.

For the control of the eating disorder of obesity and diabetes, it would have been obvious to one of ordinary skill in the art to use the device of the proposed combination to inhibit the secretion of NPY or to inhibit the effects of NPY applied in the region of the arcuate nucleus or paraventricular nucleus and the dorsal medial nucleus given

Frankish et al teaching that NPY is active in those regions and plays a vital role in those conditions.

5. Claims 9, 10, 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rise in view of Fischell et al as applied to claim 6 above, and in further view of Mondai et al (Orexins (Hypocretins): Novel Hypothalamic Peptides with Divergent Functions - article.)

The Mondai et al publication discusses the key role in the regulation of the energy balance, satiety and feeding centers of Orexins, NPY, corticotropin-releasing hormone, AGRP, melanocortin (MC3-R or MC4-R since it occurs in the brain) and gamma-aminobutyric acid (GABA), gonadotropin-releasing hormone, luteinizing hormonereleasing hormone and thyrotropin releasing hormone within the arcuate nucleus, paraventricular hypothalamic nucleus, and lateral hypothalamic regions of the brain.

Given Mondai et al's teaching it would have been obvious to one of ordinary skill in the art to inhibit the production of Orexin or the effects of Orexin on the dorsal, lateral or paraventricular hypothalamic area's or to inhibit the production of AGRP the effects of AGRP on the arcuate nucleus or inhibit the effects of a biologically active compound such as catecholamine or gamma aminobuttyric acid or stimulate the secretion of

biologically active corticotropin-releasing factor and gonadotropin-release hormone in the system of the proposed combination to treat the disorder of obesity.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rise in view of Fischell et al as applied to claim 6 above, and further in view of Bernfield et al #6284729.

Bernfield et al teaches the MC4-R is instrumental in the control of obesity (column 2, lines 47+) within the acruate nucleus.

Given this teaching it would have been obvious to one of ordinary skill in the art to promote the effects of MC4-R by stimulation in the system of the proposed combination of Rise and Fischell et al.

6. Claims 20, 23-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rise in view of Fischell et al as applied to claim 6 above, and further in view of Zabara 5540734.

Zabara discloses an implant. The reference teaches the concept of providing a closed loop system (column 5, lines 14+) that automatically activates a stimulator in response to circadian cycles and glucose levels.

Given this teaching it would have been obvious to add a closed loop feedback system to the device of the proposed combination that is responsive to the time of day or glucose levels to automate the stimulus function. To have the feedback system respond to NPY levels or other diabetic/obesity related indicators, antagonists release factors and the like as disclosed by Frankish et al would also have been obvious since they are known markers.

7. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rise in view of Fischell et al and Frankish et al as applied to claim 1 above, and further in view of Schulman et al #5193540.

Schulman et al discloses a microstimulator that can be implanted within the brain (column 3, 66+.) The device would have the obvious advantage of eliminating wires extending the tissues of the brain.

Given Schulman et al's teaching it would have been obvious to use an implantable microstimulator in the device of the proposed combination to eliminate the wires extending through tissues in the brain and thus reducing the chances of peripheral damage.

8. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rise in view of Fischell et al as applied to claim 6 above, and further in view of Schulman et al.

Schulman et al discloses a microstimulator that can be implanted within the brain (column 3, 66+.) The device would have the obvious advantage of eliminating wires extending the tissues of the brain.

Given Schulman et al's teaching it would have been obvious to use an implantable microstimulator in the device of the proposed combination to eliminate the wires extending through tissues in the brain and thus reducing the chances of peripheral damage.

9. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rise in view of Fischell et al and Zabara 5540734 as applied to claim 23 above, and further in view of Schulman et al.

Schulman et al discloses a microstimulator that can be implanted within the brain (column 3, 66+.) The device would have the obvious advantage of eliminating wires extending the tissues of the brain.

Given Schulman et al's teaching it would have been obvious to use an implantable microstimulator in the device of the proposed combination to eliminate the wires extending through tissues in the brain and thus reducing the chances of peripheral damage.

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph S. Machuga whose telephone number is 703-305-6184. The examiner can normally be reached on Monday-Friday; 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-306-4520.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1148.

Joseph S. Machuga
Examiner
Art Unit 3762

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ANGELA D. SYKES
SUPERVISORY PATENT EXAMINER
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